REMARKS

Claims 65 and 67-93 are pending.

SEQUENCES

In the Office Action, the Examiner has pointed out that when a sequence is presented in a drawing, a sequence identifier must be used either in the drawing or in the Brief Description of the Drawings. Accordingly, in the above Amendment to the Specification, the Brief Description of the Drawings on pages 6 and 7 of the specification has been amended to reflect the respective Seq ID Nos. for Figures 1, 2, 5 and 6.

SPECIFICATION

The disclosure was objected to because certain information concerning the ATCC deposits for the application was not inserted into the text of the specification. As shown above, the specification at pages 27-28 and 51 has been amended to reflect the ATCC accession numbers and date of deposit.

SECTION 112 REJECTIONS

Claims 67-76 have been rejected under Section 112, first paragraph, as being non-enabled. Applicants respectfully traverse the rejection.

It is respectfully submitted that the disclosure and working examples in the present specification fully enable the claimed methods such that the skilled artisan can achieve the methods without undue experimentation. It is not clear from the office action why references published after the filing of the present application are being applied by the Examiner. Indeed, it appears from the face of the office action that there is a conflict between the standards being applied, e.g, the Examiner would appear to be asserting that therapies for inflammation are complicated and unpredictable, and yet the references being applied for purposes of Section 102(e) are purely prophetic in nature and do not demonstrate experimentally any use for the molecule in an inflammatory condition. Further clarification of the enablement standard is respectfully requested.

PRIORITY

In the office action, the Examiner asserts that the present application is not granted benefit of priority to its provisional application no. 60/059,288. The Examiner also asserts that for prior art purposes, the effective filing date of the present application is that of its provisional application no. 60/094,640. For the reasons below, the undersigned requests that these statements regarding priority be withdrawn.

Applicants respectfully submit that the issue of priority should be held in abeyance until such a time that the patent office has a consistent and appropriate standard for assessing utility and enablement in a patent application and in art references which the office intends to apply for prior art purposes. Applicants point out that the references being applied by the Examiner in the Section 102(e) rejection (e.g., Emery et al., discussed below) disclose only certain sequence structure information. The inconsistency of patent office standards is clearly illustrated here - how can the disclosure of Emery et al. be deemed to satisfy requirements of utility and enablement and yet Applicants' provisional application 60/059,288 be found to lack specific utility? If the Examiner believes that Applicants' provisional application 60/059,288 fails to disclose specific utility, it is respectfully submitted that the disclosure of Emery et al. and Gentz et al. must be found to be similarly deficient.

Applicants do not agree with the Examiner's assertion regarding the effective filing date of the present application, and expressly reserve the right to dispute such assertion if necessary at a later time.

Section 102 Rejections

Claims 67, 68, and 71-74 were rejected under Section 102(e) as being anticipated by Emery et al. Applicants respectfully traverse this rejection.

The Emery et al. reference discloses certain sequence structure information for the TR4 molecule but fails to disclose any function or utility of the TR4 molecule. Emery et al. merely speculate what the function or activity TR4 might be, and the disclosure in Emery et al. relating to what TR4 may be used for or how it may be used is entirely

prophetic and speculative.

To anticipate, a reference must contain an enabling disclosure, and Emery et al. fails to provide an enabling disclosure for the TR4 molecule for any purpose, much less for purposes of using the molecule to treat an inflammatory condition.

Claims 67-76 were rejected under Section 102(e) as being anticipated by US 2002/0150583 (Gentz et al.; "the '583 publication"). Applicants respectfully traverse this rejection.

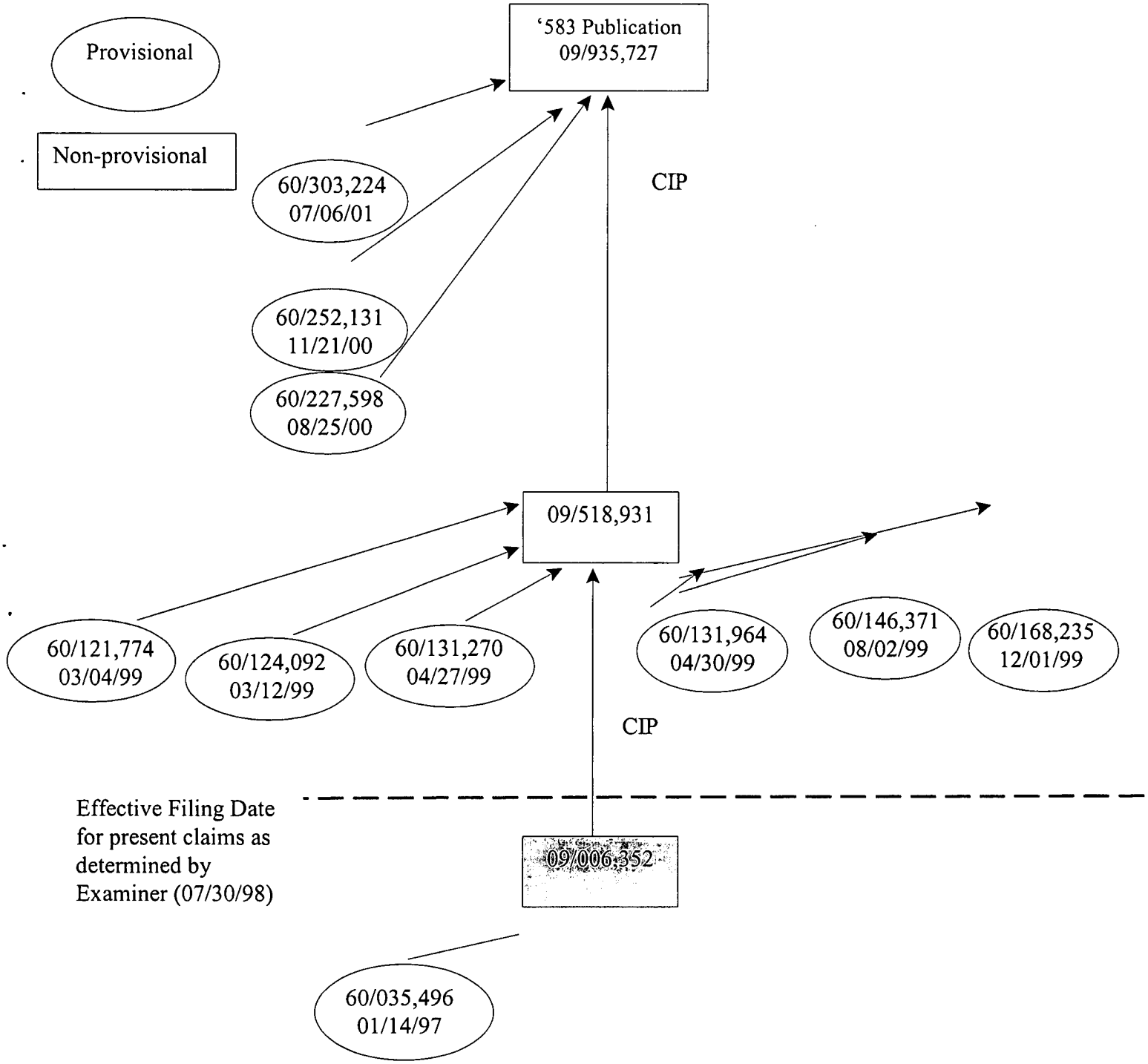
The Examiner asserts that the '583 publication teaches a TNFR-6α polypeptide (SEQ ID NO:2) that has a sequence identical to the DcR3 polypeptide (SEQ ID NO:1) of the instant application, and that the '583 publication teaches the treatment of inflammatory diseases by administering TNFR-6α. Applicant respectfully traverses the rejection for at least the following reasons.

Applicant notes that it is well-settled law that a patent (and, by implication, a patent application published pursuant to 35 U.S.C. 122(b)) shall have effect under 35 U.S.C. § 102(e) as of a particular date only to the extent that there is a sufficient disclosure under 35 U.S.C. § 112, first paragraph, for the subject matter in question. If the patent or published application claims the benefit under 35 U.S.C. §120 (and by implication under 35 U.S.C. §119(e)) to an earlier filed application, that patent or published application shall not be entitled to prior art effect under §102(e) if the earlier filed application does not provide a sufficient disclosure under 35 U.S.C. §112, first paragraph, for the subject matter in question. To be given effect under § 102(e), the claims of the reference patent must be supported in the manner required by 35 U.S.C. § 112 in the priority application whose date is relied on to establish the prior art status of the patent. *See In re Wertheim*, 646 F2d 527, 209 USPQ 554 (CCPA 1981); and MPEP 2136.03, sub-heading IV.

The '583 publication claims priority to two applications filed prior to July 30, 1998, the priority filing date the Examiner asserts for the instant application. Those two applications are U.S.S.N. 09/006,352, filed January 13, 1998 ('352 application) and U.S. provisional application No. 60/035,496, filed January 14, 1997 ('496 application). A complete "family tree" for the '583 publication relative to the July 30, 1998 priority filing date of the current

application is provided below for the Examiner's convenience. As set forth below, the neither the '352 application or '496 application fails to provide an adequate written description or enabling disclosure for the claimed methods sufficient to satisfy the requirements of § 112. Consequently, the '583 publication is not prior art to the present claims.

'583 Publication Family Tree



Neither the '496 application nor the '352 application contains experimental data characterizing the activity or function of TNFR-6α, and nor does the application identify a ligand(s) of TNFR-6α. As a matter of fact, the ligands to which TNFR-6α binds, AIM-II and FasL, were first disclosed by the applicant of the '583 publication in its 60/121,774 provisional application ("the '774 application"). See, e.g., p. 17, lines 8-10 and Example 7 of the '774 application. Such disclosures regarding the ligands of TNFR-6α are not present in the '496 or the '352 applications. Applicant notes that the '774 application was filed after the effective filing date recognized by the Examiner for the current claims.

Finally, Applicant notes that while the specification of the '496 application speculates that it may be possible to use the TNFR-6α polypeptide in essentially a laundry list of conditions ranging from cancer to HIV, such a disclosure fails to satisfy the requirements of § 112, first paragraph. Without any teaching of a function or activity of the receptor or the identity of a ligand that binds the putative receptor, the disclosure of the '496 application cannot provide an adequate written description for the pending claims, and certainly does not enable one of ordinary skill to achieve the claimed methods.

The disclosure of the '496 application indeed confirms that the applicants did not know much about the TNFR-6α molecule in terms of structure or function. For instance, the '496 application suggests that the TNFR-6α molecule is a membrane bound receptor. However, TNFR-6α is known to be a soluble decoy receptor. *See, e.g.*, Otsuki et el., Clin. Exp. Immunol., 119:323 (2000). The '496 application also states that TNFR-6α shares the highest degree of homology to TNFR-1 and TNFR-2, roughly 23%. This is a relatively low percentage of homology between DcR3 and TNFR-1 and-2. DcR3 is a soluble receptor (unlike TNFR-1 and -2 which are membrane-bound receptors) and does not have an intracellular signaling capacity. Accordingly, any inferences, if any, that can be drawn about the activity of TNFR-6α and TNFR-1 and -2 based on such homology are not a sufficient basis upon which to reasonably predict activity or function.

Accordingly, for at least the reasons set forth above, Applicant respectfully requests the Examiner to withdraw the rejection of the claims in view of Gentz et al.

Respectfully submitted,
GENENTECH, INC.

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